REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application are respectfully requested in light of the amendments above and the comments which follow.

As correctly noted in the Office Action summary, claims 1-51 are pending. Claims 17-51 were withdrawn from further consideration on the merits as being drawn to a non-elected invention.

By the present response, claims 1, 4, 11, and 12 have been amended. Therefore, upon entry of the present response, claims 1-16 await further consideration on the merits.

CLAIM REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1, 11, and 12 stand rejected under 35 U.S.C. §112, second paragraph on the grounds set forth in paragraph two of the Official Action. By the present response, Applicants have amended the above-mentioned claims in the manner suggested by the Examiner. Therefore, withdrawal of these rejections is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 1-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,437,999 to Diebold et al. (hereafter *"Diebold et al."*) in view of U.S. Patent No. 4,217,374 to Ovshinsky et al. (hereafter *"Ovshinsky et al."*) on the grounds set

forth in paragraph four of the Official Action. For at least the reasons noted below, the rejection should be withdrawn.

The present invention is directed to an electrochemical test device suitable for determining the presence or concentration of chemical and biochemical components in aqueous fluid samples and body fluids such as whole blood. The present invention utilizes amorphous semiconductor materials and printed circuit board manufacturing techniques to provide an electrochemical test device suitable for determining the presence or concentration of analytes and aqueous fluid samples. Through the use of amorphous semiconductor materials and PCB manufacturing techniques, uniform electrochemical test devices having well-defined reproducible electrode areas can be manufactured economically. The electrochemical test devices of the present invention can be advantageously manufactured by continuous roll processing, as opposed to "step and repeat" printing methods currently employed to manufacture similar devices. In addition, as noted on page four of the present specification, the amorphous nature of the electrodes formed according the principles of the present invention eliminates problems found in prior art test devices which utilize conventional conductor and semi-conductor materials, which are crystalline in nature or are noble metals and, as a result, require flat and rigid substrates to prevent cracking during manufacture, distribution or use.

An electrochemical test device instructed according to the principles of the present invention is embodied in amended claim 1. Such a device includes a non-conductive surface comprising a non-conductive coating affixed to one side of a flexible material; a

working electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said working electrode having a first electrode area, a first lead and a first contact pad; a counter electrode comprising an amorphous semiconductor material affixed to the non-conductive surface, said counter electrode having a second electrode area, a second lead and a second contact pad; and a reagent capable of reacting with the analyte to produce a measurable change in potential which can be correlated to the presence or concentration of the analyte in the fluid sample, said reagent overlaying at least a portion of the first electrode area of the working electrode.

Diebold et al., which is discussed on page two of the present specification, teaches a method of fabricating thin film electrochemical devices which are suitable for biological applications and which utilizes "step and repeat" -type photolithography to define the electrode areas. As acknowledged by the Examiner, *Diebold et al.* utilizes conventional conductor and semiconductor materials, and does not utilize the amorphous semiconductor material required by amended claim 1.

Diebold et al. discloses several embodiments of an electrochemical test device and its method of production. However, the only embodiment disclosed which includes more than one electrode is the embodiment illustrated in Figures 7A-8B. The embodiments disclosed and depicted in Figures 1-6 therein discuss an electrochemical test device having only a single test electrode and a single contact pad. Therefore, these previous embodiments fail to disclose a working electrode as well as a counter electrode as required by amended claim 1 of the present invention.

With regard to the embodiment depicted in Figures 7A-8B, the device therein fails to include certain critical features of the presently claimed invention. In the Figures 7A-8B embodiment of *Diebold et al.*, a convention noble metal conductive material 61 is deposited upon a polymer support layer 62. This coated support or metalized support 63 is then adhered to an insulating substrate 64 which is disclosed as comprising a rigid non-conductive fiberglass circuit board material, or other suitable non-conductive glass or plastic substrate (column 9, lines 16-22). A photo resist layer 65 is then applied to the metalized support layer 63. Ultraviolet light 67 is then directed through a photo mask 66 is applied to a surface of photo resist layer 65. A plurality of etching steps is then undertaken to produce an electrochemical test device which comprises the insulating substrate 64 in electrode areas defined by remaining metalized support layer area 63. A second insulating substrate 68 is applied about the electrode areas formed by the metalized support layer 63. As illustrated in Figures 8A and 8B, these areas include contact pads 69, leads 70, and electrode areas 71.

As acknowledged by the Examiner, the electrode areas of *Diebold et al.* are not formed by an amorphous semiconductor material as required by amended claim 1. Instead, the electrode areas of *Diebold et al.* are formed by conventional electrode materials as discussed in the present specification, such as a polymer support layer 62 covered with a noble metal 61. Moreover, amended claim 1 further requires a working electrode and a counter electrode both affixed to a non-conductive surface, the non-conductive surface

comprising a non-conductive coating affixed to one side of a flexible material. *Diebold et al.* also clearly fails to disclose or suggest this aspect of amended claim 1.

As noted above, Applicants have developed an electrochemical test device which utilizes amorphous semiconductor materials to form the electrodes. Through the use of such amorphous semiconductor materials it is now possible to utilize flexible substrate materials to form the electrochemical test device of the present invention, thereby enabling continuous roll processing of electrochemical test devices which is not possible with conventional chemical test devices such as the one disclose by *Diebold et al.* which requires a relatively flat and rigid substrate material in order to prevent cracking of the conventional noble metal conductive material (e.g., 61) during manufacture distribution or use. As such, the electrochemical test device disclosed by *Diebold et al.* must be produced by a more costly and tedious step and repeat processes.

Ovshinsky et al. is directed to a method of doping amorphous silicon materials which are deposited on a substrate material in order to render a film that functions in a manner similar to related crystalline materials. *Ovshinsky et al.* seeks to develop such films that can be readily applied to large surface areas in a cost effective manner and in particular is especially suited for use in the production of solar cells. *Ovshinsky et al.* is clearly not directed to an electrochemical test device or its method of production. Moreover, nowhere does *Ovshinsky et al.* address the problems associated with the use of conventional conductor and semiconductor materials in electrochemical test devices.

It is asserted that one of ordinary skill in the art would not have looked to *Ovshinsky et al.* in an attempt to modify the teachings of *Diebold et al.* absent a hindsight reconstruction assisted by Applicants own disclosure. As such, the combination is improper and should be withdrawn.

Moreover, *Ovshinsky et al.* does nothing to cure the above-noted deficiencies discussed in connection with *Diebold et al.* Nowhere does *Ovshinsky et al.* suggest substitution or an amorphous semiconductor material for conventional conductor and semiconductor materials in electrochemical test devices, or the substitution of a flexible substrate material having a non-conductive coating applied thereon which is used as a substrate for a working electrode and a counter electrode as required by amended claim 1 of the present invention.

Therefore, even if one of ordinary skill in the art were to combine the teachings of *Diebold et al.* and *Ovshinsky et al.*, the claimed invention would not result. For at least the reasons noted above, the rejection is improper and should be withdrawn.

Claims 2-16 depend from claim 1 either directly or indirectly. Therefore, claims 2-16 contain each and every limitation required by claim 1. As such, claims 2-16 are allowable over the combination of record for at least the same reasons noted above.

Application No. 08/876,812
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CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is earnestly solicited. Should the Examiner feel that any issues remain, it is requested that the undersigned by contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

Respectfully submitted,

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